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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

NEW ENGLAND CARPENTERS HEALTH BENEFITS FUND, PIRELLI ARMSTRONG RETIREE MEDICAL BENEFITS TRUST, TEAMSTERS HEALTH & WELFARE FUND OF PHILADELPHIA AND VICINITY, PHILADELPHIA FEDERATION OF TEACHERS HEALTH AND WELFARE FUND, DISTRICT COUNCIL 37, AFSCME - HEALTH & SECURITY PLAN, JUNE SWAN, MAUREEN COWIE and BERNARD GORTER, Plaintiffs, v. FIRST DATABANK, INC., a Missouri corporation, and McKESSON CORPORATION, a Delaware corporation, Defendants.	Civil Action: 1:05-CV-11148-PBS Judge Patti B. Saris

MCKESSON CORPORATION'S MEMORANDUM IN OPPOSITION TO CLASS CERTIFICATION [REDACTED VERSION]

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INTRODUCTION

Federal Rule 23(b)(3) provides a salutary gatekeeper function by foreclosing class certification for damage actions where the predominance of individual issues or problems with case management would make trial of the combined actions unfair. It was precisely on these grounds that this Court in the AWP MDL previously denied class certification for third party payor ("TPP") and consumer classes asserting inflated AWPs for self-administered drugs similar to those alleged here. *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 230 F.R.D. 61, 95 (D. Mass. 2005) ("*Pharm. III*"). For like reasons, the Court should deny certification here on each of five alternative grounds.

To start with, the ubiquitous presence of PBMs and the vigorous competition among them in the market for self-administered drugs defeats any argument of class-wide impact from alleged AWP inflation. That is the considered opinion of the court-appointed expert, Dr. Ernst Berndt. Decisively, plaintiffs' expert Dr. Hartman has candidly conceded he is unable to say Dr. Berndt is wrong. On this basis alone, certification should be denied.

Second, Dr. Hartman's concession aside, there is no empirical or economic support for the critical assumption underpinning his class-wide impact conclusion — that when AWPs are inflated all other pricing terms remain "unchanged." That assumption is contrary to industry studies and the named plaintiffs' own experience, as well as conventional economic theory underlying market pricing. Without this critical assumption, individual issues of causation predominate.

Actually, there is no need for the Court to grapple with which economic expert's theories to choose in order to deny class certification here. For, as Dr. Hartman has acknowledged, if TPPs were informed of inflated AWPs, they would take steps to eliminate their impact. The fact is that TPPs were advised of the AWP increase alleged in this case, in many instances by their own PBMs. It follows that knowledge by TPPs of the AWP increase and their responses to it, create predominantly individual issues under Rule 23(b)(3). For this reason, too, class certification should be denied.

Fourth, just as the Court found in the MDL, material terms of contracts between PBMs and their TPP clients vary widely. In the MDL, the result was that the issue of whether rebates were passed on by PBMs to TPPs broke down into a contract-by-contract inquiry. The same is true here regarding rebates which increased as AWPs increased. Far more than that, there are a host of other individual plan design issues at play here (*e.g.*, increased co-pays, reimbursement caps and the like) implemented by TPPs to defeat increased AWPs.

Finally, as this Court concluded in the MDL, individual damage trials for 11,000 TPPs in a case where aggregate damage theories are inappropriate would be nothing short of a "management nightmare." *Pharm. III* at 95. The varying state laws that must be applied compound the manageability issues even further.

For each of these independent reasons, certification should be denied.

ARGUMENT

I. PLAINTIFFS CANNOT OVERCOME THE INDIVIDUAL ISSUES OF CAUSATION THAT DEFEATED CLASSES FOR SELF-ADMINISTERED DRUGS IN THE MDL.

In the related AWP MDL case, this Court certified classes with respect to physician administered drugs but declined to certify TPP or consumer classes alleging artificial inflation in the AWPs of self-administered drugs, the very same classes plaintiffs seek to certify here. For the self-administered drug classes, the Court found that plaintiffs failed to carry their burden under Federal Rule 23(b)(3) of showing predominance of common issues with respect to causation and injury.[1] The same is true here for reasons discussed in *Pharm. III*, and for several others as well.

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[1] For class certification, plaintiffs must come forward with evidence establishing that each of Rule 23's requirements is met, *In re Initial Public Offering Sec. Litig.*, No. 05-3349-cv, 2006 U.S. App. LEXIS 29859, at *52-53 (2d Cir. Dec. 5, 2006), after examining "the claims, defenses, relevant facts, and applicable substantive law" and considering how a trial on the merits would be conducted. *Castano v. American Tobacco Co.*, 84 F.3d 734, 744 (5th Cir. 1996). Causation and injury are critical elements of each of plaintiffs' claims, and the burden of proof rests squarely on plaintiffs. For RICO, *see, e.g.*, *Anza v. Ideal Steel Supply Corp.*, __ U.S. __, 126 S. Ct. 1991, 1999 (2006) and *George Lussier Enters., Inc. v. Subaru of New England, Inc.*, 393 F.3d 36, 51 (1st Cir. 2004). For the state law claims, *see, e.g.*, *Doe v. Texaco, Inc.* No. C 06-02820 WHA, 2006 U.S. Dist. LEXIS 53930, at *8-*9 (N.D. Cal. July 21, 2006) (California Unfair Competition Law); *Wilens v. TD Waterhouse Group, Inc.*, 120 Cal. App. 4th 746,

[Footnote continued on following page.]

A. The Central Role of PBMs in the Reimbursement Transactions for Self-Administered Drugs Defeats Class Certification.

In the MDL, the critical role of PBMs in the reimbursement transactions for self-administered brand name drugs led to the Court's conclusion that individual issues of causation predominated. The same is true here.

Self-administered drugs are typically dispensed to a consumer by a retail or mail-order pharmacy, which is then reimbursed by a PBM or sometimes by a TPP. *Pharm. III* at 69. As the Court noted in *Pharm. III*, nearly all of the TPPs in the class contracted with PBMs to assist in the reimbursement process.[2] The Court determined that PBMs are the "800 pound gorillas of pharmaceutical reimbursement," and their relationships with TPPs are both heavily negotiated and highly individualized. *Id.* at 71-72.[3]

Most important, as the Court's appointed expert Dr. Berndt concluded in his Independent Expert Report in the MDL, competition among PBMs for the business of TPPs is vigorous, a view also shared by the Federal Trade Commission ("FTC"). Schechter Decl. Ex. 2A (Berndt Rep. ¶ 206.)[4] Accordingly, if published AWPs for self-administered drugs were artificially inflated, as alleged, PBMs, with their superior bargaining power, would capture any excess profit obtained by retail pharmacies and likely pass some of these savings on to their TPP clients. (*Id.*)

[Footnote continued from previous page.]

754 (2003) (California Legal Remedies Act); 73 PA. Stat. Ann. 201-9.2(a) (Pennsylvania Unfair Trade Practices and Consumer Protection Law); *Stutman v. Chemical Bank*, 731 N.E.2d 608, 611 (N.Y. 2000) (New York Consumer Protection Act); *Rusheen v. Cohen*, 37 Cal. 4th 1048, 1062 (2006) (civil conspiracy); *Chase Manhattan Bank, N.A. v. Perla*, 411 N.Y.S.2d 66, 69 (N.Y. App. Div. 1978) (civil conspiracy). McKesson also contends that plaintiffs must prove reliance to prevail on a fraud claim under RICO but acknowledges that the circuits have split on whether reliance is always required. *See Sys. Mgmt., Inc. v. Loiselle*, 303 F.3d 100, 104 (1st Cir. 2002) ("Reliance is doubtless the most obvious way in which fraud can cause harm, but it is not the only way."); *see also Pharm. III* at 92-93 (discussing circuit split). McKesson respectfully submits that First Circuit law is incorrect and wishes to preserve the question of whether reliance is a required element of fraud under RICO, and one that creates individual issues precluding certification.

[2] According to plaintiffs, "virtually all" TPPs contract with PBMs, and indeed all of the named plaintiffs were under contract with a PBM during the class period. (July 17 Mot. at 14.) [Docket No. 90.]

[3] These negotiations occur as PBMs compete for TPP clients, typically through a process in which TPPs send out requests for proposal with the assistance of benefits consultants, who then administer a competitive bidding process in which PBMs and TPPs negotiate a comprehensive package of services and financial terms. *Id.* at 72.

[4] The deposition and other evidence cited in this brief that is not already a part of the court record is all attached to the accompanying Declaration of Lori A. Schechter, and cited hereinafter as "Ex. ___."

As explained by Dr. Berndt, the result is that for self-administered drugs, causation and injury cannot be established on a class-wide basis:

> If competition among PBMs is vigorous, even if the self-administered AWPIDs were artificially inflated, injury and damages to third party payors do not follow, particularly on a class-wide basis. Since lack of competition among PBMs is crucial to Plaintiffs' theory, this would appear to undermine their allegations and certainly their assumptions of class-wide injury to damages.... Ex. 2A (Berndt Rep. ¶ 206.)

Dr. Berndt thus concluded that Dr. Hartman's (and plaintiffs') contrary views were unconvincing and inadequate:

> In summary, the Plaintiffs' theory in the context of self-administered drugs requires that competition among PBMs be insufficient to prevent injury and damage to third party payors. In my judgment Plaintiffs have not put forward a convincing argument supporting the notion that competition among PBMs is inadequate. Plaintiffs' contention is also at variance with conclusions reached by the FTC. Ex. 2A (Berndt Rep. ¶¶ 206, 209.)

Given Dr. Hartman's extensive reliance in his declaration upon Dr. Berndt's Report (*see, e.g.*, Hartman Decl. 4, n.5, 10, n.20, 12, n.28 & n.29), he was confronted at his deposition in this case with Dr. Berndt's opposing conclusions regarding class-wide impact and asked whether he could say that Dr. Berndt (and the FTC) were incorrect. He testified that he could not, conceding that his analysis to date was insufficient to contradict Dr. Berndt's conclusions.[5] Thus, as a threshold matter, plaintiffs' motion for class certification could be denied on this basis alone.

B. Dr. Hartman's Critical Assumption That Nothing Besides AWP Changed Is Seriously Flawed.

Dr. Hartman's uniform, class-wide impact theory is how plaintiffs intend to prove causation with common proof. (Pl. Br. at 6-7.) But Dr. Hartman's theory is not just at odds with

[5] Specifically, Dr. Hartman testified that he has "not done a sufficient analysis" to contradict Dr. Berndt's conclusions regarding PBM competition. Ex. 8A (Hartman Dep. 198:2-199:16). Significantly, the plaintiffs in their class brief admit that the PBM market has been "highly competitive." (Pl. Br. at 11.)

Dr. Berndt and the FTC. It is also contrary to relevant empirical evidence, conventional economic theory and even the opinion of plaintiffs' own industry expert, Susan Hayes.

The crux of Dr. Hartman's opinion is that the alleged artificial inflation in published AWPs would have inflated reimbursement to retail pharmacies but that no other pricing term (*e.g.*, discounts from AWP, dispensing fees, rebates, co-pays, etc.) would have changed over the 3½ year class period. In particular, to support his class-wide impact conclusion, Dr. Hartman assumes that apart from artificially inflated AWPs, all other pricing factors would "remain unaffected by the Scheme." (Hartman Decl. ¶ 21(b).) Yet, the fact is that throughout the class period, as AWPs rose, as explained in the accompanying Declaration of Dr. Robert D. Willig (Professor of Economics, Princeton University), the discounts off AWPs paid by TPPs also increased, *i.e.*, TPPs paid less for ingredient cost reimbursement. (Willig Expert Rep. ¶ 48.) Using contracts from the named plaintiff TPPs and others, as well as industry publications, Dr. Willig illustrates that discounts increased over time throughout the class period. (Willig Expert Rep. ¶¶ 47, 48.) Simply stated, to accept Dr. Hartman's status quo proposition requires a willing suspension of disbelief: that discounts to TPPs regularly increased in response to AWP increases except where AWPs increased due to the scheme alleged in this case.[6]

Dr. Hartman's "unaffected" assumption also flies in the face of conventional economic theory. As Dr. Willig explains, under well accepted economic principles, an artificial increase in published self-administered AWPs will necessarily lead to a number of pricing changes affecting TPPs, including larger reimbursement discounts, lower dispensing fees and increased rebates, as well as cost-shifting to others. (*See, e.g.*, Willig Expert Rep. ¶¶ 36-38, 77-99, 124-25.) AWP is not the price paid by TPPs, it is just the starting point. The actual prices paid by TPPs are determined via the discounts off AWP, rebates, and various fees that are contained in contracts

[6] At his deposition, Dr. Hartman was asked to provide "all of the reasons" why he believed discounts and dispensing fees would "remain unaffected" and whether he had conducted a study to confirm his view. In response, he testified only that he assumed no change based on what he had seen in the market and "I have not done that study for putting forward this formulation." Ex. 8A (Hartman Dep. 375:20-376:11.)

between PBMs and pharmacies and between PBMs and TPPs. (Willig Expert Rep. ¶¶ 22-26.) In order to determine what effect there is on actual prices when one of the market conditions changes, as in this case, AWP, the standard economic approach would be to compare realized prices to those from the situation that would have held *but for* the artificial change in AWP. Dr. Hartman does not do so, and thus he has no basis for concluding that other contractual terms, such as the discount off of AWPs in TPP contracts will remain constant as AWPs are artificially inflated. Dr. Willig explains that economists would expect exactly the opposite. (Willig Expert Rep. ¶¶ 35-37.)[7]

Indeed, even plaintiffs' industry expert, Susan Hayes, disagrees with Dr. Hartman. Ms. Hayes originally was listed along with Dr. Hartman as one of two experts plaintiffs designated regarding causation and damages for class certification. Ms. Hayes is a long-time consultant to TPPs, and has been held out by plaintiffs as an expert regarding the effect of increased AWPs upon TPPs. At her deposition, she agreed that the year-to-year increase in discounts off AWP achieved by TPPs during the class period could be attributed to the increase in AWPs pursuant to the scheme alleged in this case:

> Q. Can you think of any other reason why the discounts have gotten larger over time other than the fact that the cost of drugs went up?
>
> A. Well, I think now looking back on it, I think it was because the spread between WAC and AWP has increased.
>
> Q. Because of the allegations in the complaint?
>
> A. Yes.

[7] As Dr. Willig explains, the reason why discounts off AWP are apt to increase is that the artificial inflation in AWPs did not change fundamental facts affecting the determination of actual market prices: the level of competition did not change; the cost of production did not change; and determinants of demand did not change. All that changed was the artificial starting price: AWP. Once AWP increases, other mechanisms are triggered to restore reimbursement rates to their previous levels. (Willig Expert Rep. ¶¶ 35-36.)

Ex. 10A (Hayes Dep. 221:9-16.) Not surprisingly, plaintiffs withdrew Ms. Hayes after her deposition.[8]

In sum, plaintiffs have no viable theory for proving uniform, class-wide impact and damages. This is thus another ground for denying plaintiffs' motion for class certification.

II. KNOWLEDGE BY TPPS OF THE ALLEGED INCREASE IN AWPS IS ANOTHER REASON FOR DENYING CERTIFICATION.

As Dr. Willig demonstrates, individual issues of causation predominate whether or not TPPs were aware of the alleged scheme to increase AWPs. (Willig Expert Rep. ¶¶ 51-62.) Significantly, even Dr. Hartman acknowledges that if TPPs were aware of inflated AWPs they would have taken immediate steps to ameliorate the price increase. That was Dr. Hartman's position regarding claims made in the MDL lawsuit and that same proposition would apply equally here, as Dr. Hartman has recently acknowledged. The result is that individual issues of knowledge by TPPs of AWP increases and TPP responses to them, create predominatingly individual issues even under Dr. Hartman's thesis.

A. Dr. Hartman Concedes that TPP Knowledge Is Relevant to Determine Whether Impact From the Scheme Is Uniform.

Respecting the claims made in the MDL, Dr. Hartman was asked in his deposition in this case how TPPs would have responded had they known that AWPs had been artificially inflated by the defendant manufacturers as alleged in the MDL. Dr. Hartman testified that TPPs would have said "I'm not going to pay you AWP less 15. I'm going to negotiate more aggressively." Ex. 8A (Hartman Dep. 83:11-13; 82:14-83:13; *see also* 84:10-12.) Later, in more colorful language he amplified his opinion:

> If they knew about this bid of excess fees, you know, there's going to be heat-seeking missiles that go and compete them away.

Id. (Hartman Dep. 83:19-21.)

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[8] In their amended class motion papers, which this Court allowed so plaintiffs could add analysis with respect to their re-alleged consumer class, plaintiffs took the opportunity to entirely rewrite their motion with respect to the TPP class, and to withdraw Ms. Hayes' declaration in support of their motion.

Obviously, the same proposition applies here respecting the alleged scheme to inflate AWPs. Indeed, more recently, in connection with the proposed FDB settlement, Dr. Hartman submitted a declaration which rests upon this very theory.[9] Specifically, as part of the proposed settlement, FDB agreed to lower published AWPs for self-administered drugs currently based upon a 25% markup over WAC to a new published price of 20% over WAC. In his supporting declaration, Dr. Hartman states that with knowledge of the change from 25% to 20% markup, it is likely that not all reduced costs will be passed on to TPPs since it is possible "that retailers would attempt to renegotiate the percentage discount off FDB's AWP to defeat the reduction in the allowed amount to be reimbursed." (Hartman Settlement Decl. at 5 n.14.) Subject to this "exception," Dr. Hartman finds that:

> It is highly unlikely that the *interested market participants* will be able to reverse and defeat the effects of the settlement *within one year* . . . .

(*Id.* fn. 19; emphasis added.) Apparently, after one year all bets are off. As observed by Dr. Willig, Dr. Hartman's one-year no-change thesis is directly at odds with Dr. Hartman's opinion in his supporting class declaration where he assumes that no changes will occur at all during the entire 3½ year class period. (Willig Expert Rep. ¶ 49.)

B. There is Ample Evidence that TPPs Were Aware of the Five-Percent Increase in AWPs.

There is ample evidence that TPPs observed the increase in AWP spreads on their own, or learned about them during the class period from a variety of industry sources.

TPPs learned of FDB's increased WAC-AWP spreads from their PBMs. Express Scripts, one of the three largest PBMs in the country, observed FDB's changed ratios in the early months of 2002. Express Scripts discussed the changed spreads with drug manufacturers and directly with FDB; it performed analyses of the impact of the change; and it determined not only which drugs' WAC-AWP spreads went up, but also which drugs' spreads went down. Significantly,

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[9] *See* Declaration of Raymond S. Hartman Impact and Cost Savings of the First Databank Settlement Agreement, dated September 27, 2006 [Docket No. 123] ("Hartman Settlement Decl.").

Express Scripts then provided written notification of FDB's WAC-AWP spread increases to its TPP clients.[10] As Express Scripts stated in notifications to clients in April of 2002 entitled [redacted]

[redacted][11]

Caremark, another of the largest PBMs, also observed in 2002 changes in the spreads or ratios between WAC and AWP published by FDB. Gregory Madsen, for example, the Senior Vice President of Retail Services at Caremark, and the person responsible for negotiations of Caremark's contracts with pharmacies, took these increased spreads into account when he proceeded to negotiate Caremark's contracts with pharmacies. Ex. 4A (Madsen Decl. ¶¶ 1-3.)

Other TPPs learned about the increase in WAC-AWP spreads from claims processors and claims administrators. [redacted] Similarly, [redacted][12]

Still others observed the spikes in FDB's AWPs on their own. Thus, [redacted] observed the WAC to AWP spread changes in January 2002 through its internal monitoring of rebates; it then independently confirmed the change it observed with the drug maker Astra Zeneca.[13] Such observations are hardly surprising since, as Dr. Hartman concedes, "[a]nybody

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[10] Ex. 6B (Declaration of Christina F. Macinski ¶¶ 3-5).

[11] Ex. 6F (ESI-414-00001753-54); *see also* McKesson's Response to Plaintiffs' Proffer of Evidence and Counter-Proffer Regarding Evidence on Individual Issues ("Proffer") ¶¶ 8-18. Examples of the kinds of evidence that bear on this Court's class certification analysis are discussed in the numbered paragraphs contained in McKesson's accompanying Proffer.

[12] For the details of the audit report, *see* Proffer ¶¶ 19-20.

[13] *See* Proffer ¶ 21.

could observe it on a day-to-day basis if they chose to" because both AWP and WAC were published prices.[14] Ex. 8A (Hartman Dep. 55:13-24.) Moreover, once the AWP increases were observed by some industry participants, this knowledge would have been disseminated to others. As Dr. Berndt concluded, and this Court previously noted, "the patterns of diversified ownership and heterogeneous scale and scope of operations among PBMs . . . make[] it difficult for any important information to remain uncovered on a sustained basis." Ex. 2A (Berndt Rep. ¶ 133); *see also Pharm. III* at 71-72.

Even TPPs who did not specifically learn that the WAC-AWP spreads had changed were still on notice that the AWPs had increased in absolute terms relative to their historical trends — a fact that was widely reported in the industry.[15] These reports instructed TPPs on how to mitigate the effects of AWP increases through various plan design changes.[16] [redacted][17]

C. The Issue of TPP Knowledge of the AWP Increase Therefore Defeats Class Certification.

Which TPPs became aware of the AWP increases alleged in this case? Which TPPs use, in Dr. Hartman's words, "heat seeking missiles" to immediately compete these increases away?

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[14] Many TPPs, particularly large and sophisticated TPPs, subscribed to First Databank and therefore received WAC and AWP pricing information directly from First Databank. *See* Proffer ¶ 22. Moreover, as Dr. Willig explains, the anomalous increase in AWPs in 2002 was readily apparent from TPPs' claims data, which would have shown jumps in AWPs for top-selling, high-profile drugs like Lipitor. (Willig Expert Rep. ¶ 65 (noting jump in Lipitor's AWP as shown in the claims data of named plaintiff Teamsters Health and Welfare Fund).)

[15] Proffer ¶ 24 (describing spike in AWPs in 2002 published in industry reports by Medco, Caremark, and Express Scripts consistent with the spikes in AWP shown in the graphics in the Second Amended Complaint and the Hartman Declaration.) (SAC ¶ 10; Hartman Decl. ¶ 15, fig. 1.)

[16] Proffer ¶ 39.

[17] *See* Proffer ¶¶ 14, 7. (describing MEDCO 00195).

These and many more related questions constitute individual issues that make class certification impossible under Rule 23(b)(3). At trial, McKesson would be entitled to probe every TPP to determine whether anyone at the TPP was aware of the AWP increase, when they learned of this information, what actions they took in response, and when.

The plaintiffs' response to all this so far has been to argue that from the depositions of TPPs to date, none have testified that they were aware of the AWP increases. (Pl. Br. at 2, 6, 12-13.) Whether or not discovery to date proves that TPPs knew of the AWP increases is irrelevant; a motion for class certification is not meant to resolve merits issues. *In re Polymedica Secs. Litig.*, 432 F.3d 1, 16-17 (1st Cir. 2005). What's more, as shown, there is a substantial body of evidence that TPPs did know. In the end, the real benefit of plaintiffs' argument is to underscore the host of individual issues at stake here arising out of the issue of knowledge.

More than that, the issue of individual knowledge also completely undermines Dr. Hartman's class-wide injury opinion. Exactly how does Dr. Hartman address this fatal defect in his class-wide impact opinion? He simply takes the expedient route of testifying that he was told to assume no knowledge by any TPP anytime over the 3½ year class period. Ex. 8A (Hartman Dep. 351:6-10; 346:1-351:10.) Since his assumption is wrong, so too is Dr. Hartman's conclusion of class-wide impact.

III. TPPS' UNIQUE CONTRACT TERMS WITH PBMS AND INDIVIDUALIZED PLAN DESIGNS THEMSELVES CREATE PREDOMINANTLY INDIVIDUAL ISSUES.

PBMs had a variety of measures available during the class period to counteract the impact of rising AWPs. These included contractual and plan design features that automatically defeated AWP increases, as well as steps that, when taken proactively, defrayed increased prescription drug expenses. As the Court held in the MDL, because of the "variability in TPPs' contracts with PBMs," plaintiffs would be unable to show that "each TPP class member paid more than it would have in the absence of the fraud via common proof." *Id.* Here, the Court will need to examine a long list of factors as they played out across 11,000 TPPs and 3½ years to determine whether any particular payor was impacted by increased AWP-WAC spreads, and if

so, by how much. As in the MDL, individual issues with respect to causation and damages predominate over common ones.[18]

A. Various Built-in Mechanisms In Prescription Drug Benefit Programs Automatically Counteracted the Impact of Increased AWPs.

Without any knowledge or action by TPPs, various mechanisms built into TPP-PBM contracts and drug benefit programs would have automatically counteracted the increase in AWPs alleged in this case. Manufacturer rebates are an obvious example.[19] Because some manufacturer rebates are based on AWP, an increase in AWPs would also increase rebates to PBMs and in turn TPPs. For example, [redacted] (Proffer ¶ 25.) This Court already found that the impact of rebates cannot be assessed on a class-wide basis. As this Court found in *Pharm. III:*

> The contractual relationship between each TPP and each PBM may commonly reference AWP as the benchmark, but there the similarity ends because the contracts provide different bundles of services and rebates.

Pharm. III at 95. The same is true here.

Prescription drug benefit plans likewise included a variety of provisions that immunized TPPs from AWP increases, and that raise the same kinds of individual issues presented by rebates. For example, many plans excluded from coverage categories of Appendix A drugs, such as oral contraceptives like Loestrin, or drugs that are also available over the counter like Prilosec. (Proffer ¶¶ 36, 37.) Because consumers paid the full cost for drugs not covered by their plans, TPPs bore none of the impact of AWP increases for these prescriptions. Other plans "capped"

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[18] *See, e.g., Robinson v. Texas Auto Dealers Ass'n*, 387 F.3d 416 (5th Cir. 2004) (reversing a conditional class certification in RICO action where alleged overcharge may have been eliminated through individualized negotiations); *In re Methionine Antitrust Litig.*, 204 F.R.D. 161, 165-67 (N.D. Cal. 2001) (denying class certification where expert's formula assumed uniform rate of pass-through, but the evidence showed a range of pass-through rates in the industry)

[19] Plaintiffs concede that rebates are individualized. *See* July 17 Mot. at 13 ("each of the drug manufacturers separately negotiated with each of the PBMs to set the rate of rebates for the drugs they provide, and each PBM separately negotiated with its clients (the TPPs) whether and to what extent rebates would be passed on to them.").

reimbursements for brand drugs that are also available in generic form, like Claritin. (*Id.* ¶ 38.) Under a plan with a generic cap, if a consumer bought the brand instead of the generic equivalent, the consumer paid the full difference in cost. (*Id.*) As with drugs excluded from coverage, TPPs would not have paid a penny more for Appendix A drugs subject to a generic cap. Because these factors varied by plan and by drug, as well as over time, this Court would need to look at specific coverage provisions and actual utilization for *each* plan offered by *each* of the 11,000 TPPs over the *entire* 3½ year class period. As with rebates, these individualized inquiries regarding the impact of increased AWPs on causation and damages preclude a finding of predominance.

B. TPPs Could and Did Take Measures To Counteract the Impact of Increased AWPs.

1. TPPs Responded to Rising Drug Costs By Renegotiating the Terms of Their PBM Contracts.

TPPs responded to increasing prescription drug costs throughout the class period by renegotiating the reimbursement terms of their contracts with PBMs. Indeed, for many TPPs, the relevant consideration was increased cost of reimbursement — not the change in the WAC-AWP markup. (Proffer ¶ 33.) For these TPPs, the key fact was that one component of net costs — AWP — had gone up more than expected. Regardless of how they were triggered, the evidence shows that as a result of these negotiations, average discounts off AWP for retail brand drugs increased significantly during the class period. (*Id.* ¶ 28.)[20]

Many PBM contracts with TPPs contained provisions that either permitted or mandated renegotiation in response to changing market conditions. For example, two named plaintiffs, [redacted] and New England Carpenters, had PBM contracts that required the parties to

[20] As discussed in Professor Willig's export report, because these discounts applied to all brand name prescription drugs, an average increase in the discount off AWP of as little as 2.5% potentially could counteract the entire economic impact of the alleged Scheme. (Willig Expert Rep. ¶ 117.) Indeed, as reported by [redacted]

attempt to negotiate an equitable pricing adjustment in response to a material change in drug industry practice. If the parties were unable to agree on new terms, the agreement was terminable on 60 days notice. (*Id.* ¶ 26.) Similarly, the agreement between [redacted] and its PBM called for retroactive pricing changes in response to any event that affected total contract cost by more than 3/4%. (*Id.*) Still other contracts were terminable without cause on short notice. (*Id.* ¶ 31.) Yet other contracts provided protection through "most-favored pricing" clauses that guaranteed that the PBM's pricing would be competitive with the pricing offered to similarly situated TPPs. (*Id.* ¶ 27.)

Even where the contracts did not mandate adjustments or allow termination without cause, TPPs could and did renegotiate pricing terms. TPPs monitored drug costs on a regular basis throughout the class period. When costs went up, they requested and obtained better pricing. For example, during the second year of a three-year contract, named [redacted] requested and received substantial concessions on ingredient costs for brand name drugs by mail order, administrative fees at retail and mail, formulary management, and mail order dispensing fees — all effective May 1, 2003. Thereafter, effective January 1, 2004, [redacted] requested and received additional discounts on ingredient costs. (Proffer ¶ 28.) Other TPPs had similar experiences. Indeed, plaintiffs' former industry expert, Susan Hayes, conceded that TPPs as a group were able to obtain greater discounts throughout the class period in response to higher AWPs. (Proffer ¶ 32.)

To determine the extent to which any particular TPP was able to defray increases in AWPs through pricing concessions from its PBM, this Court will need to examine all the contracts and amendments governing each TPP's relationship with its PBM throughout the class period. As Dr. Hartman testified, "how that sorted itself out with negotiations is anybody's guess." Ex. 8A (Hartman Dep. 190:22 -191:11.)[21] The need for individualized proof of these

[21] Dr. Hartman makes no adjustment in his damages formula for a change in discounts or dispensing fees (Hartman Decl. ¶ 21(b)), and he testified that whether PBMs negotiated steeper discounts with pharmacies and passed them on

[Footnote continued on following page.]

matters, rather than guesswork, weighs heavily against any finding that common issues predominate.

2. TPPs Responded to Rising Drug Costs by Changing the Terms of Their Benefit Plans.

Prescription drug costs had been escalating at rates above inflation well before the class period. In response, PBMs and benefit consultants urged plan sponsors to revise their benefit plan designs to increase individual member's responsibility for drug costs by, among other things, increasing co-payments, imposing reimbursement caps, or instituting or raising deductibles. (Proffer ¶ 39.) TPPs' responses varied widely — different sponsors adopted different strategies and plan design features at different times and to varying degrees. (*Id.* ¶¶ 39-42.) To the extent that they shifted costs to their members through these mechanisms, plan sponsors effectively mitigated the alleged impact on the TPP class of increased WAC-AWP spreads. (Willig Expert Rep. ¶¶ 93-99; Proffer ¶¶ 39-42.) Whether and how this cost-shifting occurred raises yet another series of inherently individual factual inquiries.

Plaintiffs concede the effectiveness of these cost-shifting mechanisms in seeking certification of a consumer co-payment class. Indeed, the claims of the consumer class rest on the fact that TPPs did not absorb the full impact of AWP increases; consumers with percentage co-payments bore a share of the increase in WAC-AWP spreads through their direct payments at the pharmacy. Other proactive changes in plan design over the class period worked in the same way to shift some or all of increased AWPs away from TPPs. For example, many plan sponsors increased flat co-payments in response to higher drug costs.[22] For a 30-day supply of an Appendix A drug dispensed at $100, a co-payment increase of as little as $5 would be sufficient to negate the impact of the alleged scheme on the TPP class. The effectiveness of these

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[Footnote continued from previous page.]

to TPPs is "irrelevant to what I've been asked to do here, so I haven't pursued it." Ex. 8A (Hartman Dep. 190:7-198:24.)

[22] This was accomplished by various means. Some sponsors raised the nominal dollar amount of the co-payments. Others added additional tiers with higher co-payments, or moved particular drugs into non-formulary classifications that required patients to pay higher non-preferred co-payments. (Proffer ¶¶ 40-41.)

measures is not hypothetical. [redacted]

(Proffer ¶ 28.) Plaintiffs fail to account for any of these individualized cost-shifting mechanisms in their class-wide impact analysis.

Instead, plaintiffs erroneously contend that plan design is "legally irrelevant" because RICO concentrates the right of recovery in the "directly injured party." (Pl. Br. at 20.) But plaintiffs cannot dispute that damages under RICO are limited to injuries actually sustained. *See Bonilla v. Trebol Motors Corp.*, 150 F.3d 77, 87 (1st Cir. 1998); *Commercial Union Assurance Co. v. Milken*, 17 F.3d 608, 612 (2d Cir. 1994). Here, the impact of higher WAC-AWP spreads was distributed, among others, between TPPs and consumers through various plan design features that determined who bore what share of the out-of-pocket costs for a prescription. Indeed, the proposed consumer class exists precisely because they claim to have been directly injured when the dollar amount of their percentage co-payments at the pharmacy went up as a result of the AWP increase. This same principle applies to all of the other varying mechanisms built into a TPP's benefits plan that shifted the impact of AWP increases from the TPP itself onto others.[23] Individual issues of impact and injury from these varying mechanisms provide another basis to deny certification of any class.

[23] Plaintiffs' cases directly contradict their position. For example, in permitting insurers to recover for payments made on behalf of patients who used a fraudulently promoted diabetes drug, the Second Circuit was careful to note that "each HBP and its patient co-payer has its own, segregable, claim for economic harm, to the extent of their respective co-pay." *Desiano v. Warner-Lambert Co.*, 326 F.3d 339, 350 (2d Cir. 2003). Likewise, in *Blue Cross & Blue Shield United of Wisc. v. Marshfield Clinic*, 65 F.3d 1406 (7th Cir. 1995), the Seventh Circuit held that Blue Cross could recover for medical services it paid directly, but that "if the patients paid the entire fees to the Clinic and then were reimbursed in whole or in part by Blue Cross . . . [then] only the patients could sue." *Id.* at 1414. *Accord Blue Cross and Blue Shield of N.J., Inc. v. Philip Morris, Inc.*, 36 F. Supp. 2d 560, 569-70 (E.D.N.Y. 1999) (right of recovery under RICO "devolves to the injured [party] which *initially* sustained the economic damages") (emphasis added). Finally, *In re Warafin Sodium Antitrust Litigation*, 212 F.R.D. 231, 258 (D. Del. 2002), limited the TPPs' recovery to 82% of the settlement, with the balance going to consumers who directly paid for the subject drug.

IV. MANAGEABILITY PROBLEMS LIKEWISE PRECLUDE CLASS CERTIFICATION.

Plaintiffs cannot overcome the manageability problems posed by both proposed classes.[24] Plaintiffs propose to adjudicate class-wide liability and aggregate damages in an initial Part I trial, and to award the aggregate proceeds to the two classes in Part II. (Pl. Br. at 15.) This litigation, however, is not susceptible to an aggregate damages approach, and as this Court concluded in the MDL, "[h]olding 11,000 individual damages trials in Part II is a management nightmare." *Pharm. III* at 95. The nightmare includes far more issues than the Court addressed when denying certification for the same classes in the MDL.

A. Plaintiffs' "Aggregate Damages" Methodology Is Legally Flawed.

Plaintiffs seek to avoid the manageability problems inherent in this litigation by adjudicating damages in the "aggregate." Courts routinely reject the use of aggregate damage formulas, like Dr. Hartman's, where they lead to overstatement of damages or fail to consider relevant factors.[25] This Court so held with respect to the formula plaintiffs proposed for classes involving self-administered drugs in the MDL. The same is true here. As Dr. Willig's declaration explains, Dr. Hartman's proposed formula is based on the critical assumption that no other contract term or market condition changed in the 3½ year class period as a result of artificially inflated AWPs. (Willig Expert Rep. ¶¶ 36, 77-99, 124-25.) This seriously flawed

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[24] Rule 23's manageability inquiry "encompasses the whole range of practical problems that may render the class action format inappropriate for a particular suit." *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 164 (1974). Assessing manageability requires an inquiry into "the form that trial on the[] issues would take." *Simer v. Rios*, 661 F.2d 655, 672 (7th Cir. 1981).

[25] *Sikes v. Teleline, Inc.*, 281 F.3d 1350, 1365 (11th Cir. 2002) (reversing certification of RICO class because aggregate damages calculation would "allow recovery . . . greater than that caused by the offending conduct"); *Bell Atlantic Corp. v. AT&T Corp.*, 339 F.3d 294, 304-05 (5th Cir. 2003) (denying certification because aggregate formula failed to account for "[n]umerous factors"). *See also* 3 Newberg on Class Actions § 10:2 (4th ed. 2002) ("[a]ggregate damage proofs are valid and proper only when proved and determined by the same standards by which the propriety of individual awards are decided."). The cases plaintiffs cite are not to the contrary. *See Schwab v. Philip Morris USA, Inc.*, No. CV 04-1945 (JBW), 2005 U.S. Dist. LEXIS 27469, at *30 (E.D.N.Y. Nov. 14, 2005) (approving of aggregate damages "[s]o long as the trial plan provides for an accurate means of assessing a defendant's liability"); *In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 235 F.R.D. 127, 143 n.55 (D. Me. 2006) (approving of an aggregate approach "[i]f the plaintiffs have an adequate model to award aggregate damages").

assumption grossly overstates purported damages by failing to account for the steps TPPs and PBMs took to counteract the impact of rising costs. This Court found Dr. Hartman's aggregate damages formula for the self-administered TPP and consumer classes in MDL "unsatisfactory because the aggregate damages per drug calculated in Phase I are likely to be too high." *Pharm. III,* 230 F.R.D. at 95. Not surprisingly, Dr. Hartman testified at his deposition that he could not quantify how close his aggregate damages approach would come to actual damages when computed on an individual-by-individual basis. Ex. 8A (Hartman Dep. 352:12-354:23.)

The "management nightmare" this Court identified in the MDL is compounded here for several reasons. First, in the MDL, this Court anticipated that it would have to look at varying rebate provisions in 11,000 TPP-PBM contracts. Here, the contract analysis would have to include contract provisions between each TPP and its PBM over the class period, not just for rebates, but for all the other terms that Dr. Hartman *assumed* would remain "unchanged," such as discounts off AWP, dispensing fees, and administrative fees. Whether any employee of a TPP had knowledge of the alleged 5% increase, and whether subsequent changes in any one contract term resulted from that knowledge would also have to be explored. Beyond that, each damages trial would also have to address the multiple plan design changes implemented by 11,000 TPPs to adjust for rising AWPs, which Dr. Hartman admits he does not take into account. *Id.* (Hartman Dep. 224:3-226:17, 239:9-18.)

Second, on top of the TPP contract examination, detailed sales transaction records for each Appendix A drug dispensed during the class period would need to be examined to eliminate all prescriptions billed at the pharmacies' usual and customary prices whenever these U&C were below discounted AWP. While the size and frequency of U&C discounts, as well as the drugs to which they applied, varied over time and by geographic location, PBMs estimated that, all told, 8%-10% of the prescriptions dispensed through their retail networks were priced at U&C rather than AWP. (Proffer ¶ 43.) Neither TPP nor consumer class members, by definition, could have been damaged by drugs reimbursed at U&C rates.

Third, contrary to Dr. Hartman's assumptions, not all TPPs paid reimbursements based on FDB's data. (Proffer ¶ 44.) The source of AWP data matters, because it was recognized within the industry that AWPs were not uniform among publishers. (*Id.* ¶ 45.) Thus, the Court would need to scrutinize each TPP-PBM contract to identify which contracts required or permitted use of a source of AWP other than FDB. Then, individual reimbursements that were based on those other sources would need to be excluded from the computation of damages.

B. The Variability in State Laws Will Also Make Certification Unmanageable.

Consistent with this Court's MDL determination, plaintiffs will not be able to apply California law to the claims of all TPPs and consumers nationwide, and must instead apply the laws of the states where plaintiffs reside. (*See* Opp'n to Pls.' Mot. for Determination of Applicable State Law.) Courts routinely deny certification on manageability grounds for this reason alone.[26] Plaintiffs urge, however, that "certification is still appropriate" because "the Court may certify subclasses of claims based on state laws with essentially the same requirements." (Pl. Br. at 16 n.27, 19) Yet plaintiffs have completely failed to satisfy their burden to "demonstrate through an extensive analysis that grouping is feasible." *Pharm. III* at 84 (citation omitted). Plaintiffs' simplistic charts fail to do so. (*See* Berman Decl. Exs. 51-53.)

For example, the Court previously denied certification of a nationwide TPP class because many states do not permit corporations to sue under their consumer protection laws. Plaintiffs' failure to propose a grouping based on this fundamental distinction was fatal to certification of the TPP class in the MDL, and should be so here. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 233 F.R.D. 229, 231-32 (D. Mass. 2006).

Similarly, the failure to propose a grouping to account for key differences in standards for reliance and causation precludes certification of the consumer class. Plaintiffs do not dispute that these standards vary materially by state. Moreover, unlike the co-payments under Medicare

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[26] *See, e.g.*, *Sikes*, 281 F.3d at 1367; *In re Bridgestone/Firestone Tires Prods. Liab. Litig.*, 288 F.3d 1012, 1018 (7th Cir. 2002).

that this Court addressed in *Pharm. III*, which are uniform nationwide, co-payments under private prescription benefit plans vary depending on two key variables: the specific terms of each individual plan *and* the effectiveness of measures by each plan sponsor to counteract the impact of rising AWPs. Thus, unlike the physician-administered Medicare class in *Pharm. III*, to determine whether a member of the self-administered consumer class in this case was impacted by an increase in AWP markups (and if so by how much), the Court will need to apply standards of reliance and causation that vary by state, to a complex set of facts that vary by plan and over time. The result is a management quagmire.

CONCLUSION

Much of plaintiffs' support for certification is based on their claims that McKesson and FDB conspired to inflate AWPs. Of course, as a matter of law, these liability assertions are irrelevant at the class certification stage, and have been vehemently denied by both McKesson and FDB in any event.[27] Plaintiffs' smokescreen of charges cannot obscure what is abundantly plain: for a multitude of compelling reasons taken together or independently, class certification of plaintiffs' damage action is unwarranted in this case.

Respectfully submitted,

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Dated: January 24, 2007.

[27] *See* Proffer at 1-3.

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the above document was served upon the attorney of record for each other party through the Court's electronic filing service on January 24, 2007.

/s/ Lori A. Schechter
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